



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#856
11-25-B

Serial No. : 09/975,786
Filed : October 11, 2001
Applicant : Norman F. Sheppard, Jr., et al.
Title : Microchip Reservoir Devices and
Facilitated Corrosion of Electrodes

TC/AU : 3763
Examiner : M.K. Han

Docket No. : 17509-0020
Customer No. : 29052

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TECHNOLOGY CENTER R3700

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John T. Santini, Jr., hereby declare that:

1. I am an inventor of the above-identified patent application. I am a Founder of and current President and Chief Scientific Officer of MicroCHIPS, Inc., which is the assignee of the patent application. I have over 10 years experience working in the field of developing micro-reservoir drug delivery devices, which in one aspect may include electrochemically driven corrosion mechanisms for opening the reservoirs to release its drug contents.

2. I have reviewed the Office Action mailed July 29, 2003, in connection with the patent application. I am intimately familiar with the two prior art references cited therein, Santini, Jr. et al., *Angew. Chem. Int. Ed.*, 2000, 39, 2396-2407 ("the Santini article") and U.S. Patent No. 5,787,898 to Santini Jr., et al. ("the Santini patent"), as I am the primary author and inventor of the respective references.

3. The Santini article does not disclose or suggest applying a time-varying potential, through an electrochemical cell, to a primary electrode to corrode the primary electrode. The Office Action is incorrect in stating (at page 2) that the Santini article “discloses ... “a method for applying a time-varying potential.” Figures 2, 3, 7, and 10 of the Santini article do not teach or suggest a time-varying potential. Figure 10b shows the rate of drug release from a microchip varying over time, but this is not due to varying the potential. The Santini article also does not remotely disclose or suggest that a time-varying potential should be characterized by a waveform having a maximum potential effectively anodic to meet or exceed the corrosion potential of the primary electrode.

4. Neither the Santini article nor the Santini paper disclose or suggest a microchip device that includes a means for applying a time-varying potential to the primary electrode in an amount effective to corrode the primary electrode when placed in contact with an electroconductive fluid, wherein the means comprises a counter electrode.

5. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such

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willful false statements may jeopardize the validity of the application or any patent issuing thereon.


JOHN T. SANTINI, JR.

Oct. 24, 2003
Date